Remarks

Rejection Under 35 U.S.C. § 112, first paragraph

Claims 1, 5, 15 and 19 were rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor had possession of the claimed invention. Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

The Legal Standard

The general standard for the written description requirement is that "a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention." *See* M.P.E.P. § 2163(I). All that is required is that the specification provides sufficient description to reasonably convey to those skilled in the art that, as of the filing date sought, the inventor was in possession of the claimed invention. *Union Oil of California v. Atlantic Richfield Co.*, 208 F.3d 989, 997, 54 U.S.P.Q.2d 1227, 1232 (Fed. Cir. 2000); *Vas Cath*, 935 F.2d at 1563-64. An applicant may show possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). As noted in a recent decision by the Board of Appeals and Interferences, the written description requirement does not require a description of the complete structure of every species within a chemical genus. (*see Utter v. Hiraga*, 845 F.2d

993, 998, 6 U.S.P.Q.2d 1709, 1714 (Fed. Cir. 1988), stating "A specification may, within the meaning of 35 U.S.C. § 112, para. 1, contain a written description of a broadly claimed invention without describing all species that claim encompasses.").

An adequate written description of the invention may be shown by any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention. *Id.*, citing *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1323, 56 USPQ2d 1481, 1483 (Fed. Cir. 2000); *Pfaff v. Wells Electronics, Inc.*, 55 U.S. at 66, 119 S.Ct. at 311, 48 USPQ2d at 1646.

Although the "written description" requirement is a separate requirement from the "enablement" requirement, if the enablement requirement has been met, it is difficult for the Examiner to assert that the written description requirement has not similarly been met. The Federal Circuit recently expressed this in *LizardTech Inc. v. Earth Resource Mapping, Inc.*, stating "A recitation of how to make and use an invention across the full breadth of the claim is ordinarily sufficient to demonstration that the inventor possesses the full scope of the invention and vice versa." *LizardTech Inc. v. Earth Resource Mapping, Inc.*, 424 F.3d 1336, 1343, 76 U.S.P.Q.2d 1724, 1732 (Fed. Cir. 2005). Applicants note that the Examiner has withdrawn his rejection of the claims of the present application for lack of enablement.

Analysis

Claims 1, 5, 15 and 19 Meet the Written Description Requirement

Written description is determined from the perspective of what the specification conveys to one of ordinary skill in the art. *In re GPAC Inc.*, 57 F.3d 1573, 1579, 35 U.S.P.Q.2d

1116,1121 (Fed. Cir. 1995); *Vas Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 U.S.P.Q.2d 1111, 1117 (Fed. Cir. 1991). The applicants have clearly described the peptide as defined by the claims with such particularity that one of skill in the art would clearly recognize that applicants were in possession of the peptides as defined by the claims. The peptide is defined by structure (i.e. a specific length and comprising a specific sequence) as well as function.

The Examiner cites *Fiers v. Revel* ((CAFC, 1993) 25 USPQ2d 1601) and *Amgen v. Chugai* ((CAFC, 1991) 18 USPQ2d 1016) to support his statement that "adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it." In both cases the courts held that "a claim to a product having a particular biological activity or function....is not conceived until one can define it other than by its biological activity or function....While one does not need to have carried out one's invention before filing a patent application, one does need to be able to describe the invention with particularity." The present application is clearly different from these cases because the peptides are not defined only by biological activity.

The claimed peptides are derived from the known amino acid sequence of human WT-1 (see at least page 8, lines 9-10 of the specification) and comprise the amino acid sequence RMFPNAPYL, wherein the peptides are presented by HLA-A0201 on antigen-presenting cells (APCs) (see page 8, lines 15-24 and Example 1 on page 39). In other words, the peptides contain RMFPNAPYL flanked by N-terminal and/or C-terminal extensions derived from the amino acid sequence of human WT-1 polypeptide. The claimed peptides encompassed by the

scope of the claims are easily identified by a person of ordinary skill in the art based upon the following structural features "common to the genus."

1) the peptide contains the known sequence of human WT-1 polypeptide;

2) the peptide contains RMFPNAPYL, N-terminal and C-terminal extensions derived from the sequence of WT-1; and

3) the sequence can be processed by HLA-A0201-positive antigen presenting cells (APC) resulting in the HLA-A0201 bound RMFPNAPYL. Furthermore, the claimed peptides have a defined length of at least 9 but fewer than 100 amino acids.

The application, as originally filed, clearly illustrates that intact WT1 protein is processed by antigen presenting cells, thereby producing RMFPNAPYL (which is recognized by CTL). This indicated that RMFPNAPYL, in the context of WT1-derived flanking sequences can be cleaved by proteasomes and aminopeptidases to give rise to RMFPNAPYL. As discussed above, the peptides as defined by the claims are clearly defined in the specification by their structural **and** functional features. Therefore, claims 1, 5, 15 and 19 satisfy the written description requirement.

Rejection Under 35 U.S.C. § 112, second paragraph

Claims 1, 5, 7, 15 and 19 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for recitation of the phrase "HLA-A0201-positive antigen presenting cells." Applicants respectfully traverse this rejection.

The Examiner argues that the phrase "HLA-A0201-positive antigen presenting cells" is unclear as to whether the antigen presenting cells (APCs) are professional or non-professional

APCs. The Examiner also argues that the phrase is unclear because professional and non-professional APCs process peptides differently.

It is irrelevant whether the APCs are professional or non-professional. It does not matter which way the peptides are processed. As defined by claim 1, all that is required is that the peptide be capable of being processed by an APC to produce a peptide having the sequence RMFPNAPYL. Therefore, the claims encompass only those peptides that are processed by HLA-A0201-positive antigen presenting cells (APC) to produce the HLA-A0201 bound RMFPNAPYL. The application, as originally filed, clearly illustrates that intact WT1 protein is processed by antigen presenting cells, thereby producing RMFPNAPYL. This indicated that RMFPNAPYL, in the context of WT1-derived flanking sequences, can be cleaved by proteasomes and aminopeptidases to give rise to RMFPNAPYL. One of ordinary skill in the art would readily realize that peptide precursors containing RMFPNAPYL and WT1 flanking sequences would be processed by HLA-A0201 antigen presenting cells whether they are professional or non-professional and give rise to RMFPNAPYL bound to HLA-A-0201. The Examiner has provided no evidence that different methods of processing of WT-1 derived peptides by professional vs. non-professional APCs yields peptides other than RMFPNAPYL bound to HLA-A-0201. Therefore, claims 1, 5, 7, 15 and 19 are clear and definite.

Rejection Under 35 U.S.C. § 102

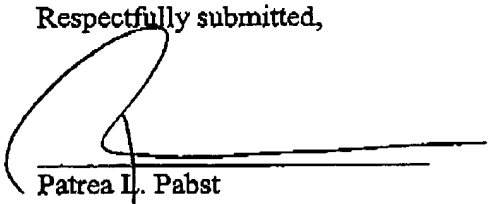
Claims 1, 5, 7, 15, and 19 were rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent Application Publication No. 20030082196 by Gaiger, et al. ("Gaiger"), which claims

priority to U.S. Patent Application No. 09/164,223, ("the '223 application") filed September 30, 1998. Applicants respectfully traverse this rejection.

In the Response to Office Action mailed, Applicants enclosed a Declaration Under 37 C.F.R. § 1.131 by Hans Josef Stauss and Liquan Gao demonstrating that prior to September 30, 1998 they conceived and reduced to practice the peptide containing the amino acid sequence RMFPNAPYL. The Examiner has objected to this Declaration as failing to state the location of the reduction to practice and as failing to provide evidence of the sequence of the peptides. A revised signed Declaration is enclosed. The Declaration has been revised to state that the location of the reduction to practice was in London, United Kingdom, a member of the World Trade Organization. While the previously filed Declaration clearly states that the peptide containing the amino acid sequence RMFPNAPYL is represented in the laboratory notebook pages (Exhibit B) as WT-1/126, the revised Declaration states that the Applicants manually scanned the amino acid sequence of human WT-1 to identify candidate peptides with predicted HLA-A2 anchor residues. These candidate peptides (Exhibit A) were chemically synthesized, not eluted from cells. Following chemical synthesis, the candidate peptides were incubated with cells in the assays as described in the Declaration and shown in the laboratory notebook pages (Exhibit B). RMFPNAPYL is designated as mu WT 126-34 in Exhibit A and WT-1/126 in Exhibit B. The revised Declaration clearly demonstrates that the applicants had conceived of and reduced to practice peptides containing the amino acid sequence RMFPNAPYL prior to September 30, 1998. Therefore, Gaiger is not available as prior art under 35 U.S.C. § 102(e).

Allowance of claims 1, 5, 7, 15, and 19 is respectfully solicited.

Respectfully submitted,



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